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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

----- X

Echo Bay Pharmaceuticals, LLC,

Plaintiff,

-v-

Torrent Pharma, Inc.,

Defendant.

----- X

1:20-CV-06345-BCM

**DEFENDANT'S REPLY IN SUPPORT
OF ITS MOTION TO DISMISS THE
FIRST AMENDED COMPLAINT**

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INTRODUCTION

The contract at issue is titled a “Co-Development Settlement Agreement” (“CSA”). The very title embodies its purpose—a framework by which Echo Bay and Torrent agreed to co-develop pharmaceutical products. Echo Bay balks at this shared responsibility and even chastises Torrent for “seek[ing] to recast the parties . . . as ‘co-developing’ certain generic drugs.” ECF No. 44, Pl.’s Opp’n to Mot. to Dism. (“Opp’n”) 3. Echo Bay claims Torrent’s references to co-development are “plainly misleading” and asserts that Torrent “knows its ‘co-development’ story is a myth.” *Id.* at 3, 18 n.14. Such a characterization by Torrent is hardly misleading; co-development is the agreement the parties made—in both form and substance.

The fundamental flaw in Echo Bay’s logic is the juxtaposition of Echo Bay’s certainty that the CSA requires Torrent to complete “necessary, prudent and reasonable” development and obtain ANDA approval by specific GDUFA goal dates with Echo Bay’s inability to explain where these terms can be found in the CSA. Echo Bay resorts to scouring the CSA for terms it claims embody these obligations. There is a reason such terms are impossible to find—that was the deal the parties made.

Echo Bay seeks to recast the parties’ roles and now claims that “[h]aving developed a number of formulations of generic pharmaceuticals, Echo Bay engaged [Torrent] to develop, manufacture, sell and distribute such products.” Opp’n 1. Whatever “a number of formulations” means (an allegation absent from the FAC), Echo Bay’s suggestion that it “engaged” Torrent to undertake certain activities is at odds with the co-development framework. That framework, not Echo Bay’s rhetoric, controls.

Not only does the CSA provide a framework for co-development, the CSA also provides a framework for ceasing development—section 8.4. *See* ECF No. 38, FAC Ex. A. Echo Bay discards section 8.4 as a “red herring” because “the FAC makes clear that Torrent never ceased

Development efforts.” Opp’n 4. Setting aside that Echo Bay’s original complaint alleged the exact opposite,¹ Echo Bay never grapples with how the presence of section 8.4, which articulates the parties’ rights if one party ceases development, permits Echo Bay to claim “damages in excess of \$15 million dollars,” instead of resorting to its rights under section 8.4. FAC ¶ 103.

Echo Bay’s theories are an attempt to re-write the deal the parties struck and re-cast itself as bearing no risk of unsuccessful development. The Court should reject Echo Bay’s effort to avoid the terms to which the parties agreed and dismiss the FAC with prejudice.²

ARGUMENT

I. Echo Bay’s Defenses of Its Express Breach Theories Are Unavailing

A. Echo Bay Fails to Show that the “Obligations” it Claims Torrent Did Not Perform in Compliance with Law Exist in the First Place

Echo Bay does not really engage with Torrent’s explanation for why Echo Bay has not plausibly alleged breach of sections 7.1(c) and 9.5. FAC Ex. A. Instead, Echo Bay asserts, “[t]hat FDA regulations are applicable to Torrent’s obligations in developing pharmaceuticals for which it seeks FDA approval is axiomatic, uncontroversial, and not in dispute.” Opp’n 7. Echo Bay’s assertion does not address whether the parties imported all FDA regulations into the CSA.

The CSA provides that the parties’ performance of their “obligations hereunder” cannot “violate . . . applicable laws or regulations,” FAC Ex. A, § 7.1(c), and that each party must “comply with all . . . laws . . . applicable to its obligations under” the CSA, *id.* § 9.5. Both terms require Echo Bay to first identify Torrent’s “obligations” and then explain why Torrent’s

¹ The Court is entitled to consider the conflict between Echo Bay’s original complaint and those in the FAC. See *Pichardo v. Only What You Need, Inc.*, No. 20-CV-493 (VEC), 2020 WL 6323775, at *3 n.5 (S.D.N.Y. Oct. 27, 2020); ECF No. 42, Def.’s Mot. to Dism. (“Opening”) 18–19.

² Echo Bay accuses Torrent of referencing facts outside the pleadings, pointing to Torrent’s identification of the signatories to the CSA and Torrent’s reliance on Supreme Court cases and FDA explanations of how the generic pharmaceutical approval process works. It is appropriate for the Court to consider these background facts to understand the voluminous documents Echo Bay attached to the FAC.

performance of those obligations did not comply with the law. The purported obligations Echo Bay identifies—obtaining FDA approval within a particular timeframe and manufacturing products at a specific site in Levittown—are absent from the CSA.

Sections 7.1(c) and 9.5 do not create these obligations, nor do they apply to Torrent’s activities in seeking FDA approval or operating its Levittown facility. Echo Bay conflates Torrent’s development of products under the CSA with Torrent’s manufacturing of other drugs. Echo Bay blends statements in the FDA’s February 20, 2019 Complete Response Letter, which relates to the parties’ co-development of pyridostigmine, *see* FAC Ex. G, with the FDA’s October 28, 2019 Warning Letter, which references Torrent’s manufacturing of finished drugs that have nothing to do with Echo Bay, *see* FAC Ex. I. Opp’n 7. Echo Bay’s desire for the Court to read these documents together highlights why sections 7.1(c) and 9.5 apply only to Torrent’s “obligations” under the CSA. Torrent did not agree that all of its FDA interactions could form the basis of a claim for breach.

Echo Bay highlights the over breadth of its interpretation of sections 7.1(c) and 9.5 by stating “it is axiomatic that a pharmaceutical product must be approved by the FDA prior to distribution – and failure to satisfy FDA requirements results in a lack of such approval.” Opp’n 10.³ Thus, in Echo Bay’s view, *any* “failure to satisfy FDA requirements” is a violation of law subjecting Torrent to liability for breach of contract. If the parties intended this strict liability, they would not have hidden it in generic terms.

³ Echo Bay also claims Torrent “cites no case that holds” *ejusdem generis* can be “an aid to contract interpretation” and that the canon cannot apply when specific words follow general words. Opp’n 9. Echo Bay is mistaken. *See* Opening 11 (citing *Team Mktg. USA Corp. v. Power Pact, LLC*, 839 N.Y.S.2d 242, 246 (N.Y. App. Div. 2007)).

B. Section 3.3's Requirement that Torrent Be "Responsible to the FDA" Does Not Create Development Milestones the Parties Did Not Adopt

Echo Bay argues that section 3.3 required Torrent to be "responsible to" the FDA (which Torrent does not dispute), instead of explaining how the phrase "responsible to" gives rise to the obligations Echo Bay claims Torrent breached. Echo Bay argues that it is "curious" that Torrent would suggest "that Section 3.3 only required Torrent to 'be responsible to' the FDA for 'Development activities', but not actually requiring it to perform such activities."⁴ Opp'n 11. Echo Bay no longer alleges Torrent did not perform development activities at all; Echo Bay now asserts Torrent failed to engage in "necessary, prudent and reasonable" development, Opening 18–19, and breached the CSA by "failing to obtain ANDA approvals for the Active Products on or before the respective GDUFA dates for such Active Products," among other things, FAC ¶ 110(a). The ease with which these purported obligations can be articulated in Echo Bay's brief and the FAC shows they also could have easily been drafted into the CSA. But they cannot be found in section 3.3 (or anywhere else). They do not spring from Torrent's general agreement to be "responsible to" the FDA.

C. The Court Should Dismiss Echo Bay's Claim for Reimbursement of Expenses It Will Not Say Whether It Paid

In two complaints and one opposition brief, Echo Bay never says whether it paid "all or some" of the \$197,300 Nines Consult Pharma invoice, of which it claims Torrent owes \$98,650. *See* Opp'n 14; FAC Ex. L. Echo Bay asserts Torrent is responsible for 50% of the invoice "[e]ven if Echo Bay only paid for part of its obligation." Opp'n 14. Echo Bay does not know

⁴ Echo Bay also contends that "[t]he FAC and its Exhibits, including the CSA, uniformly demonstrate that Torrent, alone, was the developing party – not merely 'responsible to' the FDA, but the party actually undertaking and performing Development efforts." Opp'n 12. This is irrelevant to the meaning of "responsible to" and notably at odds with both Echo Bay's CEO Rajin Ahuja's inclusion in the email chains Echo Bay filed with the FAC, as well as Echo Bay's argument that it can claim reimbursement of "Development Expenses." Opp'n 13; FAC Ex. A at 18, Ex. K.

whether it paid “all or some” of the Nines invoice because of “accounting discrepancies.” *Id.* Echo Bay cannot sue for damages it has not suffered.

Echo Bay also leaves unaddressed Torrent’s explanation regarding how the CSA does not obligate Torrent to reimburse Echo Bay for Development Expenses. *See* Opening 12–13. Echo Bay quotes language from section 3.1 stating the parties will bear Development Expenses “50/50,” but Echo Bay ignores that section 3.1 describes only Echo Bay reimbursing Torrent. Opp’n 13. Schedule 1.6 lists costs of which the parties will “bear 50%,” but does not contradict the framework in section 3.3. *Id.* Echo Bay relies on emails it claims show “Torrent’s receipt of” the services in the invoice, but the emails do not explain the meaning of the CSA. *Id.*

D. Torrent Has Rebutted Every Theory of Breach Echo Bay Claims Occurred

Echo Bay accuses Torrent of “trivializ[ing] the robust allegations in the FAC” by addressing the express CSA terms Echo Bay claims Torrent breached. Opp’n 14. Echo Bay states those terms are sections 1.6, 3.1, 3.2, 7.1(c), 8.4, and 9.5. Opp’n 14–15. Torrent addressed each of these sections in its opening brief, and explained why the Court should dismiss the FAC despite their existence. The Court should not permit Echo Bay to move forward when Echo Bay has failed to successfully explain why Torrent breached any express term.

II. Echo Bay’s Theories About Implied Terms Fare No Better

A. Torrent Did Not Concede that the CSA Contains the Terms Echo Bay Urges

Echo Bay repeatedly argues Torrent has conceded that the Court should infer the duties Echo Bay claims the CSA implies. *See* Opp’n 8 n.8, 15. Echo Bay is confused. Torrent does not dispute the existence of the implied covenant of good faith and fair dealing. That implied covenant simply does not give rise to the duties Echo Bay wants it to. *See* Opening 14–23. Echo Bay argues that its “allegations in the FAC make clear the CSA includes such implied duties imposed upon Torrent, including reasonable efforts and diligence in Developing and

Commercializing the Active Products, which Torrent breached.” Opp’n 15. But it is not Echo Bay’s allegations from which the Court infers duties, it is the contract.

B. Echo Bay’s Allegation of an “Exclusive License” Does not Make It So

Echo Bay argues that its allegation that section 2.2 amounted to an “exclusive license” is sufficient to survive a motion to dismiss, even though section 2.2 does not contain that phrase. Echo Bay is wrong; the Court should rely on the CSA, not Echo Bay’s contradicting allegations. *See Subaru Distribs. Corp. v. Subaru of Am., Inc.*, 425 F.3d 119, 122 (2d Cir. 2005).

Instead of grappling with section 2.2’s text, Echo Bay analogizes the CSA to the agreement in *New Paradigm Software Corp. v. New Era of Networks, Inc.*, No. 99 Civ. 12409, 2002 WL 31749396, at *1 (S.D.N.Y. Dec. 9, 2002). Opp’n 16. *New Paradigm* concerned the sale of a computer program “for over \$2 million plus a continuing 5% royalty on future” sales of the program. *Id.* at *1. Unlike the generic pharmaceuticals Echo Bay and Torrent agreed to co-develop, the *New Paradigm* software already existed. *See id.*; Opening 21–23. The CSA also has no analogue to the 5% royalty. Echo Bay agreed to receive an “Echo Bay Net Revenue Share” but also agreed to a disclaimer of any warranty that Commercialization would result “in any minimum amount of Echo Bay Net Revenue Share payments.” Opening 20.⁵ New York law’s treatment of contracts by which “ongoing commissions or royalties are to be paid in an exclusive arrangement” is irrelevant here. *See* Opp’n 16.

⁵ Echo Bay suggests a “reasonableness requirement” exists “even in the absence of an exclusive license or royalty agreement,” citing *RCN Telecom Servs, Inc. v. 202 Ctr. St. Realty LLC.*, 156 Fed. App’x. 349 (2d Cir. 2005) (unpublished). Opp’n 17 n.13. *RCN Telecom* was a landlord-tenant dispute regarding whether rent paid to the wrong party had to be returned and whether “the walk-away clause in the contract was RCN’s exclusive remedy in the event of appellant’s failure to provide sufficient electricity or whether appellant breached the contract.” 156 Fed. App’x. at 351. *RCN* has nothing to do with Echo Bay’s case.

C. The Court Does Not Need to Resolve any Ambiguities to Dismiss the FAC

Without actually pointing to any supposedly ambiguous language, Echo Bay argues that “if the Court were to find relevant provisions of the CSA ambiguous,” it should deny Torrent’s motion. Opp’n 18. Neither side argues any term at issue in this motion is ambiguous. The fact that the parties have competing interpretations of the CSA does not render it ambiguous. *See Aurelius Capital Master, Ltd. v. Republic of Argentina*, No. 19 CIV. 351 (LAP), 2020 WL 70348, at *6 (S.D.N.Y. Jan. 7, 2020). The Court does not need to consider alleged ambiguities Echo Bay has not identified.

D. Echo Bay’s Alleged Implied Terms Conflict with the CSA’s Express Terms

1. The Alleged Implied Terms Conflict with Section 8.4

Echo Bay misreads section 8.4 and misunderstands its significance. Echo Bay asserts section 8.4 requires Torrent to provide written notice if it ceases to contribute Development Expenses. Opp’n 19. Yet section 8.4(a) can be triggered “[r]egardless of whether or not [Torrent] provides such written notice.” FAC Ex. A. Echo Bay asserts section 8.4 “permits only cessation of contribution of development expenses – not cessation of Development work.” Opp’n 14. This overlooks section 8.4(a)(ii), which if triggered, results in Echo Bay receiving, among other things, “the right to complete the Development.” FAC Ex. A.

Textual errors aside, it is the *presence* of section 8.4 in the CSA, not whether it was triggered, that is relevant to this motion to dismiss. Echo Bay continues to believe it can plead around section 8.4 by alleging “that Section 8.4(a) was never invoked,” or alternatively “that Torrent is in breach of the CSA even if Section 8.4(a) were invoked, due to its failure to comply with Section 8.4(b) [sic].” Opp’n 19. This misses the point. Echo Bay cannot state a claim for breach premised on Torrent ceasing development when section 8.4 expressly permits Torrent to do so. *See* Opening 18-20. If section 8.4(a) is triggered, Echo Bay becomes entitled to various

assignments, not the monetary damages Echo Bay seeks here. Echo Bay cannot sidestep this express term via “implied” terms.

2. The Alleged Implied Terms Conflict with the Warranty Disclaimers

Attempting to avoid the CSA’s two disclaimers of warranties, Echo Bay relies on *Cruz v. FxDirectDealer, LLC*, 720 F.3d 115, 124 (2d Cir. 2013), to argue the disclaimers cannot obviate Torrent’s purported obligation to “undertake good faith efforts to Develop and Commercialize the Active Products.” Opp’n 20. The contract in *Cruz*, however, contained an express “best efforts” clause. 720 F.3d at 118. The CSA does not. Echo Bay asserts section 7.2 “recognizes the application of other representations elsewhere in the CSA,” Opp’n 20, but only those “EXPRESSLY SET FORTH IN Article VII,” FAC Ex. A, § 7.2. Echo Bay does not invoke any express representations from Article VII. The “best efforts” duty that Echo Bay asks the Court to infer would be an implied obligation sections 2.5 and 7.2 disclaim.

3. The Alleged Implied Terms Conflict with the Integration Clause

Instead of addressing how the CSA’s integration clause can be reconciled with purported implied terms, Echo Bay resorts to arguing it should be permitted to take discovery. Opp’n 21. Section 9.1 provides that the CSA is the “entire agreement” between the parties. Echo Bay does not cite a case holding that an integration clause can only be considered at the summary judgment stage, nor does Echo Bay address the posture of *Nat’l Gear & Piston, Inc. v. Cummins Power Sys., LLC*, 861 F. Supp. 2d 344 (S.D.N.Y. 2012), in which the Court relied on an integration clause to grant a Rule 12 motion. No discovery is needed to apply section 9.1

E. The Intent and Purpose Element of an Implied Covenant Claim is Well-Established and Not Limited to “Earn Out” Cases

Echo Bay attempts to minimize the intent element of an implied covenant claim by partially quoting *Tagare v. NYNEX Network Sys. Co.*, 994 F. Supp. 149, 159 (S.D.N.Y. 1997):

Under New York law, every contract contains an implied covenant of good faith and fair dealing. This covenant includes an implied undertaking on the part of each party that he will not *intentionally and purposely* do anything to prevent the other party from carrying out the agreement on his part.

Id. (internal quotation marks omitted, emphasis added). Echo Bay quotes the first sentence from the above rule. Opp’n 15. Echo Bay cannot ignore the second sentence, or the body of case law on which it relies.

Tagare illustrates how allegations of ineptitude cannot satisfy the intent and purpose requirements, which is Echo Bay’s theory of Torrent’s breach of implied obligations.⁶ The cases Torrent cites recognize this requirement as a part of the basic rule of the implied covenant in New York. *See Lykins v. IMPCO Techs., Inc.*, No. 15 CIV. 2102 (PGG), 2018 WL 3231542, at *7 (S.D.N.Y. Mar. 6, 2018) (citing *Kader v. Paper Software, Inc.*, 111 F.3d 337, 342 (2d Cir. 1997); *Carvel Corp. v. Diversified Mgmt. Grp., Inc.*, 930 F.2d 228, 230 (2d Cir. 1991)). “Courts applying New York law ‘generally hold that a defendant violates the covenant of good faith and fair dealing only when he acts with some improper motive.’” *Wagner v. JP Morgan Chase Bank*, No. 06 CIV. 3126 RJS, 2011 WL 856262, at *4 (S.D.N.Y. Mar. 9, 2011). “Significantly, this standard is not satisfied by policies that are misguided or ignorant or even merely negligent.” *Id.* (internal quotation marks omitted). Echo Bay dismisses Torrent’s other authorities on this point as “earn-out” cases, and Echo Bay attempts to recast the intent and purpose requirement as a “standard of proof” unique to those cases. Opp’n 22. Yet each of the above cases describes the intent and purpose requirement in the same way—as an element of the rule, not a peculiar nuance avoidable here.

⁶ *Tagare* also recognizes that a party may not “act arbitrarily or irrationally in exercising” discretion vested in it by the contract. 994 F. Supp. at 159. Echo Bay does not assert an “abuse of discretion”-type implied covenant theory.

F. Echo Bay Fails to Explain Why the *Wood* Doctrine Applies

Echo Bay does not identify a single case in which the doctrine in *Wood v. Lucy, Lady Duff-Gordon*, 118 N.E. 214 (N.Y. 1917), was applied to parties co-developing a new product. Opp’n 17, 24. The absence of authority supporting Echo Bay is unsurprising. The *Wood* doctrine exists because “it would be unfair to place the productiveness of the licensed property solely within the control of the licensee, thereby putting the licensor at his mercy, without imposing an obligation to exploit upon the licensee.” *Vacuum Concrete Corp. of Am. v. Am. Mach. & Foundry Co.*, 321 F. Supp. 771, 773 (S.D.N.Y. 1971). This presupposes that there is “licensed property” in the first place, not an agreement to co-develop new property.

Echo Bay embraces *Automated Irrigation Controls, LLC v. Watt Stopper, Inc.*, 407 F. Supp. 3d 274, 278 (S.D.N.Y. 2019), and dismisses *Pharmaceutical Horizons, Inc. v. Sterling Drug, Inc.*, 512 N.Y.S.2d 30, 31 (N.Y. App. Div. 1987). Opp’n 23-24. Echo Bay thus suggests its agreement to co-develop generic pharmaceutical products with Torrent is more similar to the “exclusive license to exploit certain patents, patent applications, and technologies” in *Automated Irrigation* than the agreement to develop and market a new form of analgesic in *Pharmaceutical Horizons*. Elsewhere in its brief, however, Echo Bay relies on the complexity of bringing a generic pharmaceutical to market, quoting the definition of “Development” and citing the FDA’s regulatory approval process. *See, e.g.*, Opp’n 7, 11. This complexity and the attendant uncertainty of success (which the parties expressly declined to warrant) renders the CSA analogous to the agreement in *Pharmaceutical Horizons*, and the *Wood* doctrine inapplicable.

CONCLUSION

The Court should dismiss the FAC with prejudice.⁷

⁷ Although Echo Bay requested leave to amend in its brief filed November 6, Echo Bay informed the Court it would stand on its current complaint at the November 9 conference.

Dated: Minneapolis, Minnesota
November 20, 2020

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